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Court of Customs and Patent Appeals

In re Herschler

No. 78-548

Decided Feb. 1, 1979

PATENTS

1. Affidavits — In general (§12.1)

Patent and Trademark Office's physical possession of original affidavit at time of Board of Appeals' decision makes further verification unnecessary.

2. Applicants for patent — In general (§14.1)

Pleading and practice in Patent Office — Rules effect (§54.9)

Inventorship of great-grandparent application was not effectively amended by Patent and Trademark Office's acquiescence in accepting sole inventorship of grandparent, nor was great-grandparent amended nunc pro tunc by submission of copies of Rule 45 papers.

3. Specification — In general (§62.1)

Specification — Claims as disclosure (§62.3)

Specification — Sufficiency of disclosure (§62.7)

Function of description requirement is to ensure that inventor had possession, as of filing date of application relied upon, of specific subject matter later claimed by him; how specification accomplishes this is not material; claimed subject matter need not be described in haec verba to satisfy description requirement; it is not necessary that application describe claim limitations exactly, but only so clearly that one having ordinary skill in pertinent art would recognize from disclosure that applicant invented processes including those limitations.

4. Specification — Sufficiency of disclosure (§62.7)

Written description of class of compounds must provide measure of predictability for utility described for that class.

5. Pleading and practice in Patent Office — Rejections (§54.7)

It is incumbent, in first instance, for Patent and Trademark Office to give reasons why written description is insufficient.

6. Specification — Sufficiency of disclosure (§62.7)

Known steroids, when considered as class of compounds carried through layer of skin by DMSO, is not so large that single example in specification could not describe varied members with their further varied properties.

7. Specification — Sufficiency of disclosure (§62.7)

Court of Customs and Patent Appeals maintains line first clearly drawn in In re Fuetterer, 138 USPQ 217, where it found written description requirement to be satisfied where claims were drawn to rubber stock composition useful in producing tire treads, included recitation of inorganic salt capable of maintaining homogeneous distribution of another component in composition, and disclosure listed function described and four members of class having that function.

8. Claims — Specification must support (§20.85)

Specification — Sufficiency of disclosure closure (!62.7)

Principles stated in In re Driscoll, 195 USPQ 434, In re Ruschig, 154 USPQ 118, and In re Fried, 136 USPQ 429, concerning application with claims either to intermediate classes of new compounds per se or claims drawn to processes using those new compounds are still alive and well.

9. Specification — Sufficiency of disclosure (§62.7)

Claims drawn to use of known chemical compounds in manner auxiliary to invention must have corresponding written description only so specific as to lead one having ordinary skill in art to that class of compounds; occasionally functional recitation of those known compounds in specification may be sufficient as that description.

10. Patentability — Evidence of — State of art (§51.467)

Papers presented to New York Academy of Sciences could, where there is prima facie showing of obviousness to rebut, if properly presented, indicate wide-scale acceptance in art and provide secondary consideration capable of overcoming 35 U.S.C. 103 rejection.

Particular patents — Tissue Penetration

Herschler, Enhancing Tissue Penetration of Physiologically Active Steroidal Agents with DMSO, rejection of claims 1-5 and 9-13 reversed.

Appeal from Patent and Trademark Office Board of Appeals.

Application for patent of Robert J. Herschler, Serial No. 304,283, filed Nov. 6, 1972, division of application, Serial No. 69,155, filed Sept. 2, 1970, continuation-in-part of application, Serial No. 753,231, filed Aug. 16, 1968, continuation-in-part of application, Serial No. 329,151, filed Dec. 9, 1963. From decision rejecting claims 1-5 and 9-13, applicant appeals. Reversed.

Stanley M. Teigland, San Francisco, Calif., for appellant.

Joseph F. Nakamura (Fred W. Sherling and Ernest G. Therkorn, of counsel) for Commissioner of Patents and Trademarks.

Before Rich, Baldwin, and Miller, Associate Judges, and Kashiwa,* and Ford,** Judges.

Baldwin, Judge.

This appeal is from the decision of the Patent and Trademark Office (PTO) Board of Appeals (board) affirming the rejection of claims 1-5 and 9-13 in appellant's application serial No. 304,283,[1] filed November 6, 1972, for "Enhancing Tissue Penetration of Physiologically Active Steroidal Agents with DMSO."[2]

The board affirmed the examiner's rejection of all claims under 35 USC 103 as unpatentable over Lubowe in view of Faust, Marson or Brown. The board also affirmed a rejection, first entered pursuant to its authority under 37 CFR 1.196(b),[3] of each of the claims under 35 USC 102(b) or 103 over Stroughton et al., Stroughton or Kligman.[4] We reverse.

The Invention

The appellant has found that DMSO enhances the penetration of a number of materials through skin tissue. In the application at hand, a mixture of DMSO and a "physiologically active steroidal agent" is administered to skin (or a mucous membrane) with the result that the steroid penetrates the membrane. The claimed process provides such advantages as the elimination of injection by needle and the ability to administer localized doses of the drug without resort to a systemic dose.

Claim 1 is typical of the invention:

1. A method of enhancing the penetration into and across an external membrane barrier of a human or animal subject of a physiologically active steroidal agent capable of eliciting a physiological effect upon topical application thereof, which comprises the concurrent topical administration to the external membrane of an amount of said steroidal agent effective to produce the desired physiological effect and an amount of DMSO sufficient to effectively enhance penetration of said steroidal agent to achieve the desired physiological effect.

The Prior Art

The following references were relied upon to support the rejection under §103:

Lubowe Patent No. 2,942,008 issued on June 21, 1960.

Brown et al., "A Note on the Toxicity and Solvent Properties of Dimethyl Sulfox-

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* The Honorable Shiro Kashiwa of the United States Court of Claims, sitting by designation.

** The Honorable Morgan Ford of the United States Customs Court, sitting by designation.

[1] This application is a division of serial No. 69,155, filed September 2, 1970, now U.S. 3,711,606, which in turn is a continuation-in-part of serial No. 753,231, filed August 16, 1968, now U.S. 3,551,554, which is a continuation-in-part of application serial No. 329,151 (hereafter the "great-grandparent"), filed December 9, 1963, now abandoned.

[2] Dimethyl sulfoxide (hereinafter DMSO) is a water-clear, water-miscible, hygroscopic, neutral organic liquid, melting at about 18°C. and boiling at about 189°C. It is a well-known industrial solvent represented by the following formula:

[3] 37 CFR 1.196 b) provides, in pertinent part, that:

> (b) Should the Board of Appeals have knowledge of any grounds not involved in the appeal for rejecting any appealed claim, it may include in its decision a statement to that effect with its reasons for so holding, which statement shall constitute a rejection of the claims.

[4] These references were not part of the certified record transmitted to the court. However, appellant admits in his brief that the rejection is proper *if* the great-grandparent lacks a written description of the invention in issue. The contents of the references need not be considered.

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Faust, "Some New Components for Cosmetic and Dermatologic Vehicles," 77 American Perfumer 23-26 (Jan. 1962).

Marson, "Il Dimetilsolfossido Solvente Aquo-Mimetico," 102 Boll. Chimicofarm. 109-124 (Feb. 1963).

Lubowe is a patent directed to compositions with large amounts of mineral, vegetable or animal oils solubilized in short chain alcohols. The oils are maintained in solution by the addition of fatty alcohols having 10 to 24 carbon atoms. The resulting compositions may be used as a base in a number of further cosmetic and pharmaceutical compositions. When the composition is used in a hair lotion, Lubowe indicates that "estrogenic hormones, methyl sulfoxide" may be added. Example XII shows a hair lotion containing 0.1% estrogenic hormone in 50% ethyl alcohol but without DMSO.

Brown et al. shows DMSO to be a solvent in which many classes of compounds are soluble and, further, is of low toxicity.

Faust suggests that DMSO is a "safe and effective solubilizing" agent suitable for use as a cosmetic or dermatologic vehicle.

Marson cites Faust saying "the cosmetic literature has recently cited its [DMSO's] employment as simple, non-gelated components of dermatological vehicles" and describes the usefulness of DMSO in preparing pharmaceutical compositions containing, inter alia, the thickening agents such as recited in the claims.

Background

The examiner indicated in the Final Rejection and in his Answer that the claims were rejected under 35 USC 103 since "the Lubowe patent describes, inter alia, DMSO added to Ex. XII, an anti-seborrheic hair lotion containing 1/10 part by weight of estrogenic hormone," and that, "we have, inherently, the same process involved here as described in Lubowe, notwithstanding applicant's observation of percutaneous absorption from the DMSO (apparently added as a vehicle or solvent, according to Faust, Marson or Brown)."

The board, in a first opinion, agreed with the Examiner's position and amplified it, stating:

> We note that the secondary references make it clear that DMSO is an effective solubilizing agent for various drugs, including those to be applied topically and along with the examiner we emphasize that ". . . an amount of DMSO sufficient to effectively enhance penetration . . ." of the steroid is also an amount effective for solubilization of the steroid; compare with page 19 of the specification. Therefore, we find that it would be obvious to add DMSO to the steroid containing formulation of Example XII of Lubowe in amounts large enough to enhance penetration of said steroid, in view of the teachings of the secondary references regarding DMSO's utility as a solvent for topical drug formulations.

The board made an additional rejection:

> Under the provisions of 37 CFR 1.196(b) we make new grounds of rejection under 35 USC 102(b) and 35 USC 103 against claims 1 to 5 and 9 to 13.
>
> Claims 1 to 5 and 9 to 13 are rejected under 35 USC 102 and 35 USC 103 as unpatentable over any one of Stoughton et al, Stoughton or Kligman. All of the above publications were made of record by appellant's counsel in Paper No. 6 of great-grandparent case Serial No. 329,151 filed December 9, 1963. The above articles were described in detail by appellant's counsel in said Paper No. 6 (pages 8 to 12) and we will not, therefore, elaborate on the disclosure of the articles. It is sufficient to note that each of the articles teaches the enhanced penetration of various steroids resulting from topical application of DMSO concurrently with the steroid — the heart of appellant's inventive concept. All of the above articles were published in 1964 or 1965, more than one year prior to the filing date of appellant's grandparent case Serial No. 753,231, filed August 16, 1968. Hence the articles are statutory bars against the present claims under 35 USC 102(b) and 103 *unless* appellant's claimed invention was described in great-grandparent case Serial No. 329,151 filed December 9, 1963; see 35 USC 120 and 35 USC 112, first paragraph.
>
> We have carefully considered the great-grandparent case but the only disclosure relating to steroids (pages 34-35) is limited to glucocorticosteroids whereas *all* of the present claims on appeal are drawn either to steroids in general or to steroids not limited to glucocorticosteroids (claims 4-5). It is now well settled law that disclosure of a species is insufficient to provide descriptive support for a generic or sub-generic claim; In re Ruscetta et al, 45 CCPA 968, 255 F.2d

687, 118 USPQ 101 (1958), In re Lukach, 58 CCPA 1233, 442 F.2d 967, 169 USPQ 795 (1971) and In re Smith, 59 CCPA 1025, 458 F.2d 1389, 173 USPQ 679 (1972).

Hence, appellant may not rely upon his great-grandparent case to support any of the claims on appeal and thus the above articles are prior art and can be properly applied against the claims under 35 USC 102(b) and 103. We note also that the great-grandparent case was filed in the name of Jacob and Herschler, whereas the present case was filed by Herschler alone. Since the inventive entities are different, we do not see how appellant can claim priority under 35 USC 120 based upon the great-grandparent case; note the requirement that the applications be ". . . filed by the same inventor . . . ."

[Emphasis in original.]

Appellant thereupon submitted a Request for Reconsideration accompanied by two attachments and requested that the examiner consider them. The first attachment was a portion of a 508 page collection of papers given at a conference entitled Conference on Biological Actions of Dimethyl Sulfoxide held by the New York Academy of Sciences in 1974. The second enclosure was a copy of a Rule 45 declaration[5] submitted in the great-grandparent application purporting to amend the inventorship from Jacob and Herschler joint to Herschler sole.

In support of the Rule 45 affidavit, appellant argued:

> With respect to the first reason, submitted herewith are copies of papers filed under Rule 45 in the great-grandparent application, and a copy of a postcard receipt indicating that the papers were received by the Patent Office. The papers include an amendment under Rule 45 to change the inventorship of the great-grandparent application to correspond to the inventorship of this application. No notice was received that entry of the amendment was refused. Moreover, the Rule 45 papers were filed simultaneously with a continuing application in the name of the new inventorship and the Patent Office accorded continuation-in-part status to the application, which issued as U.S.P. 3,551,554. Hence, it is evident that the examiner considered the papers filed under Rule 45 and acknowledged that they were legally sufficient to change the inventorship. However, if the examiner believes it is necessary to formally change the inventorship of the great-grandparent application, he is invited to enter the Rule 45 amendment nunc pro tunc.

Appellant further argued that the written description in the great-grandparent was adequate for the subgenus now claimed:

> As clearly indicated in the great-grandparent application, appellant recognized from the start that the invention was applicable to physiologically active agents in general. * * * Thus, the Board's contention that "the only disclosure [in the great-grandparent application] relating to steroids is limited to glucocorticosteroids" is incorrect. The great-grandparent application discloses that the invention is applicable to the genus of physiologically active agents, which includes the important subgenus of steroids. A working example illustrates practice of the invention with a corticosteroid, which, of course, is a species of the subgenus of steroids. Hence, the great-grandparent application, in teaching the applicability of the invention to the genus of physiologically active agents in general, and to the species corticosteroids in particular, quite naturally describes to one skilled in the art the applicability of the invention to the subgenus of steroids. Since a corticosteroid is obviously a type of steroid, and since the word "corticosteroid" contains the very word "steroid", the corticosteroid in the working example, in view of the applicability of the invention to physiologically active agents in general, clearly represents to one skilled in the art the subgenus of steroids. There is no other subgenus that it would reasonably represent.

[5] Rule 45(b) of the Rules of Practice in Patent Cases provided, at the time of the affidavit in issue (1965), that:

> (b) If an application for patent has been made through error and without any deceptive intention by two or more persons as joint inventors when they were not in fact joint inventors, the application may be amended to remove the names of those not inventors upon filing a statement of the facts verified by all of the original applicants, and an oath or declaration as required by rule 65 by the applicant who is the actual inventor, provided the amendment is diligently made. Such amendment must have the written consent of any assignee.

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The collection of papers submitted to the New York Academy of Sciences was said to demonstrate that "in view of the interest in DMSO generated by appellant's discovery, as shown by this reference, the discovery was truly a pioneering breakthrough in medical science." And further, that the papers describing work by:

> Kligman and others with just a few different species of steroids [show], that DMSO enhances the penetration of steroids in general. This same conclusion would similarly be drawn by one skilled in the art from the disclosure in appellant's great-grandparent application. Thus, the great-grandparent application describes to one skilled in the art the invention claimed in this application.

The board remanded the application to the examiner for consideration of the appended paper. In a supplemental Answer, the examiner stated:

> The Examiner respectfully declines the invitation to either now enter, nunc pro tunc, in an abandoned application, or to even consider what precisely Stanley Jacob did, or not, co-invent, in unverified copies of submitted purported Rule 45 amendment papers, which papers, even if not untimely, are unclear: ("various embodiments", "several additional embodiments", "I was informed on July 18, 1968 that I was not a coinventor", etc.), and considers them not relevant or sufficiently precise to any specific issues herein of whether or not he did not in fact co-invent the applicable portions of S.N.329,151, filed jointly with him, which relate to DMSO topically applied with a species of glucocorticosteroid * * *. [Furthermore, the board expressly states that] "we have carefully considered.", but they found, (and appellant has not denied,) that its only disclosure relating to steroids (pages 34-35) is limited to the single species of glucocorticosteroids, whereas *all* of the present claims on appeal are drawn either to steroids in general, or to steroids not limited to glucocorticosteroids (claims 4-5), and the Board of Appeal [sic] held it to be now well settled law that disclosure of a species is insufficient to provide descriptive support for a generic or sub-generic claim, citing the Ruscetta et al, Lukach and Smith decisions. Assuming, arguendo, that the precise inventorship of said glucocorticosteroid species and DMSO is established as not involving a different inventorship question; the question remains, for review under 35 USC 141 or 145, where, in S.N. 329,151, is described the steroid genus or subgenus, now claimed? [Emphasis in original.]

The application was then returned to the board. Appellant filed another request for reconsideration reiterating the comments and arguments made in the earlier request.

The board's final opinion indicated that:

> We agree with the Examiner that the unverified and unclear papers purportedly filed under 37 CFR 1.45 do not establish that the inventorship of 329,151 and that of the instant case are the same.
>
> We have carefully reconsidered our new ground of rejection under 35 USC 102(b) and 103 over the newly cited art but we are convinced that the rejection is sound. Apart from the different inventive entities of 329,151 and the instant case we remain of the view that there is no description [in] 329,151 of the process as applicable to steroids. In In re Smith, 178 USPQ 620 (1973), there was also a description in the parent case of a broad genus and a particular species, yet the CCPA held that there was insufficient descriptive support for a subgeneric claim similar to the present subgenus claims drawn to steroids. We do not see how an article published in 1974 or 1975 can aid appellant in overcoming the deficiencies in disclosure of an application filed December 9, 1963. The fact remains that nowhere in Serial No. 329,151 is there any mention of the term "steroids," let alone a description of the claimed process as applicable to steroids as a class.
>
> We reiterate our position that claims 1 to 5 and 9 to 13 are obvious over Lubowe in view of any one of Faust, Marson or Brown under 35 USC 103. We do not agree with appellant that it would not be obvious to solubilize steroids (such as the estrogenic hormone in Example XII of Lubowe) with DMSO. As explained by the Examiner in his answer, the secondary references make it clear that DMSO is an effective solubilizing agent for various drugs, including those to be applied topically. We emphasize again that ". . . an amount of DMSO sufficient to effectively enhance penetration . . ." of the steroid is also an amount effective for solubilization of the steroid. We therefore find clear motivation from the teachings of the prior art to solubilize steroids intended for topical application by adding DMSO to steroid formulations in an

amount sufficient to solubilize components of the steroid formulation. The fact that appellant may use DMSO for a different purpose (as compared to the prior art teachings that DMSO solubilizes drugs to be applied topically) does not alter the conclusion that its concomitant use with topically applied drugs such as estrogen would be prima facie obvious from the purpose disclosed in the references; In re Lintner, 173 USPQ 560, 562 (CCPA 1972).

Opinion

35 USC 102(b)/103 Rejection over Stroughton et al., Stroughton or Kligman

As noted above, appellant concedes that the substance of this rejection is proper if the court finds either the great-grandparent application lacks a written description of the instant invention[6] or the inventorship of the great-grandparent application differs from the one on appeal. The analysis need only consider those two points.

Rule 45 Affidavit

[1] The board found that the "unverified[7] and unclear papers * * * do not establish that the inventorship of 329,151 and that of the instant case are the same." We do not agree.

Jacob's affidavit indicated that he learned of the invention from the appellant:

> Herschler disclosed at this meeting his conception of the invention of enhancing tissue penetration of physiologically active agents by applying them to animal tissue (both topically and internally) together with DMSO and his reduction to practice of various embodiments of this invention. Herschler requested at this meeting that my group test various additional embodiments of this invention for him.

and that his participation "concerning the invention disclosed and claimed in application Serial No. 329,151 was limited to assisting in further testing of the invention with such additional pharmacologically active agents."

Although the affidavit is somewhat vague regarding specific acts done by the affiant, it is quite clear that he derived all information pertinent to the disclosed invention from Herschler and acted only under Herschler's direction. The affidavit is consistent with a finding that Jacob was not an inventor in the great-grandparent application. The accompanying affidavit of Herschler (ratifying the statement of Jacob), in conjunction with the originally filed application papers, leads us to the conclusion that Herschler believes himself to be the inventor of the matter disclosed and claimed in the great-grandparent application.

[2] This is not to say that we agree with appellant that the inventorship of the great-grandparent application was effectively amended by the PTO's acquiescence in accepting the sole inventorship of the grandparent nor do we agree that the great-grandparent was amended nunc pro tunc by the submission of copies of the Rule 45 papers. We consider the affidavits sufficient, for the purpose of claiming priority under §120, to demonstrate that Jacob was joined as a coinventor through error without deceptive intent. Weil v. Fritz, 572 F.2d 856, 196 USPQ 600 (CCPA 1978); In re Schmidt, 48 CCPA 1140, 293 F.2d 274, 130 USPQ 404 (1961).

Written Description in the Great-Grandparent

The appealed claims recite a subgenus, i.e., physiologically active steroidal agents, not found in haec verba in the great-grandparent application.

Appellant emphasizes the following quotation found in the great-grandparent specification and argues that it clearly defines a genus to which the subgenus of steroids belongs:

> By the term "physiologically active substance" is meant any substance which has a demonstrable and desired physiological activity in the sense that animal tissue responds thereto. This may be an altered physiologic phenomenon following heparin administration; a pharmacological activity such as local anesthesia; an antibacterial activity following administration of antibiotics; a bacteriostatic activity following the administration of iodine; a growth stimula-

[6] We assume, in the absence of any argument to the contrary, that the parent and grandparent applications contain the necessary written description of the invention on appeal. See In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973).

[7] It is not altogether clear what is meant by "unverified" in referring to the copy of the affidavit submitted to the examiner. The PTO had physical possession of the original affidavit at the time of the board decision as is evidenced by a certified copy thereof in the transcript submitted to the court. Further verification seems unnecessary.

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dimethyl sulfoxide was p
involved area four times
days. At the end of this per
of the inflammatory rea
appeared.

This example shows a
tion of dexamethasone
when used with dimethyl

No other language in th
specifically discusses topical
steroid-containing compositi

However, the remaining
awesome in their diversity. T
emplified "physiologically
stances" includes iodine (Exa
ed pellet feed for rats (Examp
(Example 10), procaine (
various chemotherapeutic ag
17 & 18), barbiturates (Exa
insulin (Example 21), antih
ample 29), various local a
amples 34 & 35), etc.

[3] The function of the
quirement is to ensure that th
possession of, as of the filin
application relied upon, the
matter later claimed by
specification accomplishes
material. In re Smith, 481
USPQ 620 (CCPA 1973). Th
ject matter need not be des

: his participation "concerning the
ı disclosed and claimed in applica-
·ial No. 329,151 was limited to
in further testing of the invention
h additional pharmacologically ac-
ıts."

ıgh the affidavit is somewhat vague
g specific acts done by the affiant, it
:lear that he derived all information
t to the disclosed invention from
·r and acted only under Herschler's
.. The affidavit is consistent with a
hat Jacob was not an inventor in the
ındparent application. The accom-
affidavit of Herschler (ratifying the
ıt of Jacob), in conjunction with the
y filed application papers, leads us
onclusion that Herschler believes
o be the inventor of the matter dis-
ıd claimed in the great-grandparent
on.

ıis is not to say that we agree with
t that the inventorship of the
ndparent application was effective-
led by the PTO's acquiescence in
; the sole inventorship of the grand-
ır do we agree that the great-grand-
as amended nunc pro tunc by the
ɔn of copies of the Rule 45 papers.
der the affidavits sufficient, for the
ɔf claiming priority under §120, to
·ate that Jacob was joined as a
ır through error without deceptive
Veil v. Fritz, 572 F.2d 856, 196
)0 (CCPA 1978); In re Schmidt, 48
140, 293 F.2d 274, 130 USPQ 404

)escription in the Great-Grandparent

ɔpealed claims recite a subgenus,
iologically active steroidal agents,
l in haec verba in the great-grand-
ɔplication.

ant emphasizes the following
found in the great-grandparent
ion and argues that it clearly
genus to which the subgenus of
ıelongs:

he term "physiologically active
ce" is meant any substance which
demonstrable and desired
ɔgical activity in the sense that
tissue responds thereto. This may
altered physiologic phenomenon
g heparin administration; a phar-
gical activity such as local
sia; an antibacterial activity
ıg administration of antibiotics; a
ıstatic activity following the ad-
ıtion of iodine; a growth stimula-

tion activity following usual access to dietary sources, and the like. The term is intended to include any desirable pharmacological action with compounds alien to animal tissue, and any physiological activity with compounds normally occurring in animal tissue. It is also meant to include within the term "physiologically active substance" materials which are diagnostic tools such as radiopaque agents (for instance, iodine), dyes and the like.

That application exemplifies a single species within the terms of claim 1 of this appeal:

Example 30

Penetration of Corticosteroids

A twenty-four year old medical student was seen with atopic dermatitis of the right antecubital fossa. Three cc. of 100% dimethyl sulfoxide were applied four times daily for three days. No benefit was noted. One mg. or 1/4 cc. of Decadron (dexamethasone 21-phosphate) was applied four times a day for two days without benefit. One mg. of dexamethasone 21-phosphate in 3 cc. of 100% dimethyl sulfoxide was painted onto the involved area four times daily for three days. At the end of this period all evidence of the inflammatory reaction had disappeared.

This example shows an improved action of dexamethasone 21-phosphate when used with dimethyl sulfoxide.

No other language in that specification specifically discusses topical application of a steroid-containing composition.

However, the remaining examples are awesome in their diversity. The scope of exemplified "physiologically active substances" includes iodine (Example 1), pressed pellet feed for rats (Example 4), penicillin (Example 10), procaine (Example 16), various chemotherapeutic agents (Examples 17 & 18), barbiturates (Example 19), oral insulin (Example 21), antihistamines (Example 29), various local anesthetics (Examples 34 & 35), etc.

[3] The function of the description requirement is to ensure that the inventor had possession of, as of the filing date of the application relied upon, the specific subject matter later claimed by him; how the specification accomplishes this is not material. In re Smith, 481 F.2d 910, 178 USPQ 620 (CCPA 1973). The claimed subject matter need not be described in haec verba to satisfy the description requirement. In re Smith, 59 CCPA 1025, 458 F.2d 1389, 173 USPQ 679 (1972). It is not necessary that the application describe the claim limitations exactly, but only so clearly that one having ordinary skill in the pertinent art would recognize from the disclosure that appellants invented processes including those limitations. In re Smythe, 480 F.2d 1376, 178 USPQ 279 (CCPA 1973).

The question is simple: does the array of information supplied by appellant in the great-grandparent application teach one having ordinary skill in this art that one of the class of steroids will operate in the claimed process. We conclude that it does.

[4, 5, 6] A toehold on the problem is found in In re Cook, 58 CCPA 1049, 439 F.2d 730, 169 USPQ 298 (1971). The written description of a class of compounds must provide a measure of predictability for the utility described for that class. That is to say: would the worker of ordinary skill in this art consider "steroidal agents" to be operative when considering the great-grandparent's disclosure? It is incumbent, in the first instance, for the PTO to give reasons why he would not. In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 98 (CCPA 1976). The solicitor urges that the class of steroids is so large that a single example in the specification could not describe the varied members with their further varied properties. We disagree with this contention. Steroids, when considered as drugs, have a broad scope of physiological activity. On the other hand, steroids, when considered as a class of compounds carried through a layer of skin by DMSO, appear on this record to be chemically quite similar. The diversity of exemplified materials "potentiated" by DMSO in the great-grandparent application, is *much broader* than the diversity of steroid compounds shown contemporaneously in the art.[8] In this instance, we conclude that one having ordinary skill in this art would have found the use of the subgenus of steroids to be apparent in the written description of the great-grandparent application.

Were this application drawn to novel "steroidal agents," a different question would be posed.

[7] We wish to maintain the line first clearly drawn in In re Fuetterer, 50 CCPA 1453, 319 F.2d 259, 138 USPQ 217 (1963).

[8] See, e.g., Kirk-Othmer, "Sterols and Steroids," 12 Encyclopedia of Chemical Technology 917-947 (1st Ed. 1954).

There, claims drawn to a rubber stock composition useful in producing tire treads included a recitation of "an inorganic salt capable" of maintaining an homogeneous distribution of another component in the composition. The disclosure listed the function desired and four members of the class having that function. This court found the written description requirement to be satisfied:

> Appellant's invention is the *combination* claimed and not the discovery that certain inorganic salts have colloid suspending properties. We see nothing in patent law which requires appellant to discover which of all those salts have such properties and which will function properly in his combination. The invention description clearly indicates that any inorganic salt which has such properties is usable in his combination. If others in the future discover what inorganic salts additional to those enumerated do have such properties, it is clear appellant will have no control over them per se, and equally clear his claims should not be so restricted that they can be avoided merely by using some inorganic salt not named by appellant in his disclosure.
>
> We are not persuaded that our conclusion on this point is wrong by decisions of this and other courts relating to the sufficiency of invention disclosures in cases wherein the applicant is claiming chemical *compounds* per se. [Emphasis in original.]

[8] Id. at 1462, 319 F.2d at 265-266, 138 USPQ at 223. Applications with claims either to intermediate classes of *new compounds* per se or claims drawn to processes *using* those *new compounds* have been considered by this court on other occasions. In re Driscoll, 562 F.2d 1245, 195 USPQ 434 (CCPA 1977); In re Ruschig, 54 CCPA 1551, 379 F.2d 990, 154 USPQ 118 (1967); In re Fried, 50 CCPA 954, 312 F.2d 930, 136 USPQ 429 (1963). The principles stated therein are still alive and well.

[9] In sum, claims drawn to the *use* of *known* chemical compounds in a manner auxiliary to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. Occasionally, a functional recitation of those known compounds in the specification may be sufficient as that description. In Fuetterer and here, such is the case.

35 USC 103 Rejection over Lubowe in view of Faust, Marson or Brown

Throughout the Lubowe patent, DMSO is mentioned only once, and that occurs in the statement that DMSO, as well as many other enumerated compounds, may be added to hair lotion preparations containing a solubilized oil. There is no indication of why the DMSO would be added; nor is there any teaching that there is any relationship between DMSO and estrogenic hormones (which are steroids), let alone a suggestion to employ them in combination. The board relies upon the secondary references to show "that DMSO is an effective solubilizing agent for various drugs, including those to be applied topically" and accordingly finds it obvious to utilize DMSO in Lubowe's Example XII. Such a conclusion is not supported by the record, because, as appellant notes, "the formulation of [Lubowe's] Example XII is already a clear solution containing more solvent than anything else. Moreover, the alcohol solvent employed in Lubowe is also a solvent for steroids." Hence, there would have been no reason for one skilled in the art to add any additional solvent to Lubowe's formulations, particularly a totally different solvent "in any amount large enough to enhance penetration," as required by the claims. Nor would it have been obvious to one skilled in the art to substitute DMSO for a portion of the exemplified alcohols, since Lubowe's invention is directed to the use of specific combinations of alcohols in the disclosed formulations.

While the secondary references may teach that DMSO is generally useful as a solvent, there is no suggestion or teaching in any of them to combine it with a steroid — that is, to choose DMSO from among the countless number of solvents as the solvent for steroids.

[10] Appellant argues that Brown, by stating that DMSO is "not known to interfere with absorption or metabolism," is a teaching not to use DMSO. The solicitor, on the other hand, characterizes the same quotation by saying that "it is not clear how this teaching is a teaching away * * * [and, accordingly] there should be no suprise [sic] that DMSO enhances penetration." Even though that quotation from Brown cannot be said to be an overwhelming suggestion to use DMSO for any solvent-type utility, we do not see how it provides any motivation for one skilled in the art to use DMSO in the formulation of Lubowe. The references do not provide any impetus to do what appellant has done nor do they provide the

art with the knowl
enhances penetration o
through a membrane.[9]

Summary

We *reverse* the decisio
decision affirmed a rej
both under 35 USC 10

Reversed.

District Court, C.

Bohsei Enterprises C
v. Porteous Fastener

No. CV 7
Decided Nov.

TRADEMARKS

1. Fraud and misrepre

Court in Alfred Dunh
Cigar Co., Inc., 183 U
decide that omission wa
der Lanham Act.

2. Fraud and misrepre

Law of false representa
sion of material fact o
matively says in context
are sold "I am a prod
States"; concern over r
omission particularly in
goods was expressed by
enacted 19 U.S.C. 1304
articles to be "marked
place as legible, indelibly
as the nature of the art
will permit in such manr
an ultimate purchaser *
origin of the article"; to
of such material fact

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[9] We do not find it necess
tion of the weight to be given
to the New York Academy
appellant has no prima f
viousness to rebut. Were
propriate, these papers
presented, indicate wide-sca
art and provide a secon
capable of overcoming a §1

Rejection over Lubowe in view of or Brown

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art with the knowledge that DMSO enhances penetration of "steroidal agents" through a membrane.[9]

Summary

We *reverse* the decision of the board, which decision affirmed a rejection of the claims both under 35 USC 102 and 103.

Reversed.

District Court, C. D. California

Bohsei Enterprises Company, U.S.A. v. Porteous Fastener Company, et al.

No. CV 77-1241

Decided Nov. 16, 1977

TRADEMARKS

1. Fraud and misrepresentation (§67.37)

Court in Alfred Dunhill Ltd. v. Interstate Cigar Co., Inc., 183 USPQ 193, did not decide that omission was not cognizable under Lanham Act.

2. Fraud and misrepresentation (§67.37)

Law of false representation includes omission of material fact of origin that affirmatively says in context in which fasteners are sold "I am a product of the United States"; concern over materiality of such omission particularly in context of imported goods was expressed by Congress when it enacted 19 U.S.C. 1304 requiring imported articles to be "marked in a conspicuous place as legible, indelibly, and permanently as the nature of the article (or container) will permit in such manner as to indicate to an ultimate purchaser * * * the country of origin of the article"; to hold that omission of such material fact is not such false representation as to affect competition of sale to detriment of seller who complies with mandate of 19 U.S.C. 1304 requires utterly naive view of realities of market place; more importantly, it would promote disregard for provisions of 19 U.S.C. 1304; experience has taught courts that concept of private attorney general has been vigorous and needed method for protection of competition under antitrust law; to eschew the justice that experience has shown courts by a judicial narrowing of concept of fraud and deceit since it is embodied in Lanham Act would be pure legal folly and must be rejected.

Action by Bohsei Enterprises Company, U.S.A., against Porteous Fastener Co., Russell, Burdsall & Ward, Inc., Rockford Screw Products of California, Lamson & Sessions, Inc., and ITT Harper, Inc., for Lanham Act violations, and unfair competition. On defendants' motions to dismiss. Motions denied.

Ervin, Cohen & Jessup, Beverly Hills, Calif., for plaintiff.

Thorpe, Sullivan, Workman, Thorpe & O'Sullivan, Los Angeles, Calif., for Porteous Fastener Company.

Sullivan & Cromwell, New York, N.Y., and Lillick, McHose & Charles, Los Angeles, Calif., for Russell, Burdsall & Ward, Inc.

Glad, Tuttle & White, Los Angeles, Calif., for Rockford Screw Products of California.

Thorpe, Sullivan, Workman, Thorpe & O'Sullivan, Los Angeles, Calif., for Lamson & Sessions, Inc.

Powers & Tilson, Los Angeles, Calif., for ITT Harper, Inc.

Real, District Judge.

The defendants have variously moved for dismissal of the action brought by plaintiff. More specifically the motions are:

1. By defendant Rockford Screw Products of California (hereafter Rockford) — Motion for Judgment on the Pleadings.
2. By defendant Russell, Burdsall & Ward, Inc. (hereafter Russell) — Motion to Dismiss.
3. By defendant ITT Harper, Inc., (hereafter ITT) — Motion to Dismiss, Strike and for More Definite Statement.

Plaintiff Bohsei Enterprises Company, U.S.A. (hereafter Bohsei) is in the business

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[9] We do not find it necessary to reach the question of the weight to be given the papers presented to the New York Academy of Sciences in that appellant has no prima facie showing of obviousness to rebut. Were such a showing appropriate, these papers could, if properly presented, indicate wide-scale acceptance in the art and provide a secondary consideration capable of overcoming a §103 rejection.